APR 0 9 2013

K130321

5.0 510(k) SUMMARY

SUBMITTED BY:

Carol A. DePouw
Regulatory/Clinical Affairs Specialist
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 351-5850
Fax (651) 351-5669
Email: carol.depouw@diasorin.com

NAME OF DEVICE:

Trade Name:	LIAISON® Aldosterone LIAISON® Aldosterone Control Set LIAISON® Aldosterone Calibration Verifiers
Common Names/Descriptions:	Aldosterone Assay
Classification:	Aldosterone Test System: Class II 21 CFR 862.1045; Clincal Chemistry (75) Quality Control Material: Class I, reserved 21 CFR 862.1660; Clinical Chemistry (75)
Product Code:	CJM, JJX

PREDICATE DEVICE:

Siemens Coat-A-Count® Aldosterone
Reference K831178
LIAISON® 25 OH Vitamin D Control K071480
LIAISON® 25 OH Vitamin D Calibration
Verifier K090104

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® Aldosterone assay uses chemiluminescent immunoassay (CLIA) technology and is intended for the quantitative determination of Aldosterone in human serum, EDTA plasma and treated urine samples. Aldosterone measurements are intended for use in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states and other conditions of electrolyte imbalance. The test has to be performed on the LIAISON® Analyzer.

The DiaSorin LIAISON® Aldosterone Control Set is intended for use as assayed quality control samples to monitor the accuracy of the DiaSorin LIAISON® Aldosterone assay on the LIAISON® Analyzer.

The DiaSorin LIAISON® Aldosterone Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® Aldosterone assay when performed on the LIAISON® Analyzer.

KIT DESCRIPTION:

The LIAISON® Aldosterone assay is a competitive modified 2 step chemiluminescent assay that uses sheep monoclonal antibody for capture of the Aldosterone molecule. Results are determined by a 2 point calibration conversion of the master curve to a working curve. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of aldosterone present in the calibrators, controls or samples.

COMPARISON TO PREDICATE DEVICE:

Assay Similarities and Differences		
Item	New Device LIAISON® Aldosterone (k130321)	Predicate Device Siemens Coat-a-count aldosterone (k831178)
Intended Use	For the quantitative determination of Aldosterone in human serum and urine.	Same
Measuring Range	3-100 ng/dL	3-120 ng/dL
Test Principle	Chemiluminescent Immunoassay	^{125}I Radioimmunoassay
Sample size	100 µL	200 µL
Assay time	40 minutes	>18 hours
Sample matrix	Serum, EDTA plasma and 24-hour urine	Serum, 24-hour urine
Urine samples handling and processing time	1. Acid hydrolysis- 18 hrs. 2. Neutralization of urine ~2 minutes	1. Acid hydrolysis - 24 hrs. 2. Ethyl acetate extraction - 1 hr 3. Dry down ~ 15 minutes
Calibration	Two-point calibration by the user. Stable for 14 days.	7 calibrators used to generate assay curve in every assay run

Control similarity and differences		
Item	New Device LIAISON® Aldosterone Control (k130321)	Predicate Device LIAISON® 25 OH Vitamin D TOTAL Control (k071480)
Intended Use	Intended for use as assayed quality control samples to monitor the accuracy of assay.	Same
Analyte	Aldosterone	25 OH vitamin D

Matrix	Liquid Human serum based controls provided in vials with phosphate buffer, ProClin® 300 and Gentamicin.	Liquid human serum-based controls provided in vials with buffer salts and sodium azide.
Levels	Two levels: High and Low	Same
Storage conditions	2-8°C	Same

Calibration Verifier similarity and differences		
Item	New Device LIAISON® Aldosterone Calibration Verifier (k130321)	Predicate Device LIAISON® 25 OH Vitamin D TOTAL Calibration Verifier (k090104)
Intended Use	Assayed quality control materials intended for the quantitative verification of calibration and reportable range of the assay.	Same
Analyte	Aldosterone	25 OH vitamin D
Matrix	Buffered hormone free human serum based matrix (2 mL/vial) with Proclin® 300 as a preservative	Vitamin D free human serum with buffer salts and <0.1% sodium azide
Volume	2 mL	5 mL
Levels	Four levels	Same
Storage conditions	2-8°C	Same

PERFORMANCE DATA:

Method Comparison:

A method comparison study was performed on 155 serum and 106 urine samples following CLSI EP9-A2. In the study samples were tested in singlicate with the LIAISON® Aldosterone assay and in duplicate by the predicate RIA assay. Samples were collected from apparently healthy individuals. In order to cover the assay measuring range approximately 15% of the samples were spiked with enough aldosterone as needed in order to span the measuring range.

One hundred forty-four (144) of the 155 serum samples tested were analyzed. Eleven samples read below the measuring range of the LIAISON® Aldosterone assay (<3.0 ng/dL) and therefore, were not included in the analysis.The serum samples ranged from 2.62 ng/dL to 107.6 ng/dL on the RIA predicate assay and 3.02 ng/dL to 97.1 ng/dL on the LIAISON® Aldosterone assay.

One hundred four (104) of the 106 urine samples tested were analyzed. Two samples read above the measuring range of 100 ng/dL (uncorrected). The urine samples ranged from 121.9 ng/dL to 1222.3 ng/dL on the predicate RIA assay and 118.9 ng/dL to 1242 ng/dL on the LIAISON® Aldosterone assay.

Passing and Bablok regression analyses were performed for all samples across the measuring range of the assays. The results are summarized in the following table and graphs.

Sample	n	Slope	95% Confidence Interval	Intercept	95% Confidence Interval	R
Serum	144	0.98	0.94 to 1.02	1.10 ng/dL	0.43 – 1.49	0.988
Urine	104	0.98	0.91 to 1.05	34 ng/dL	11.43 to 56.7	0.948

LoB/LoD/LoQ

The Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

Results:

The limits are reported in the following table:

Detection Limits	Serum	Urine
LoB	0.97 ng/dL	1.26 ng/dL
LoD	1.45 ng/dL	2.00 ng/dL
LoQ	3.0 ng/dL	2.80 ng/dL

Reference Range/Expected Values:

Serum and EDTA Plasma:

Matched serum and EDTA plasma samples were drawn from 126 apparently healthy subjects aged 21-65 years of age with normal blood pressure and normal fasting glucose levels. Patients were fasting and drawn between 7 and 10 a.m. after being in the upright and supine positions for at least 30 - 60 minutes.

Population (126)	Median Aldosterone (ng/dL)	Observed Range (ng/dL) 2.5^{th} to 97.5^{th} Percentile
Upright (Serum)	9.80	<3.0 - 39.2
Supine (Serum)	6.76	<3.0 - 23.2
Upright (EDTA)	8.91	<3.0 - 35.3
Supine (EDTA)	6.42	<3.0 - 23.6

24 hour Urine

To assess the expected reference range, a study was performed with ninety-one (91) 24 hour urine samples. Samples were collected over a 24 hour period from individuals with a normal blood pressure result (diastolic < 85 mmHg) prior to collection. After collection, the pH and total volume of urine for each individual was measured and recorded. Urine patient results were corrected for dilution according to the LIAISON® Aldosterone Instructions for Use.

Population (91)	Median Aldosterone (µg/day)	Observed Range (µg/day) 2.5th to 97.5th Percentile
Urine (24 hour)	5.53	1.19 – 28.1

Consider these limits as guidelines only. Each laboratory should establish its own reference range

Reproducibility/Precision:

20 Day Study Design

A twenty day reproducibility/precision study was performed at DiaSorin Inc. and 2 external sites. A coded panel comprised of 6 frozen serum samples and 3 frozen urine samples was prepared by DiaSorin Inc. The 9 precision panel samples and 2 levels of controls were tested on the LIAISON® Aldosterone assay on 2 reagent integral lots at each site in two replicates per run, 2 runs per day for 20 operating days.

Results

The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens.

Reproducibility/Precision Results – Combined 3 site

Sample ID	N	mean conc ng/dL	Within run		Total across Lots and across Sites	
			SD	%CV	SD	%CV
KC 1	480	6.8	0.24	3.5%	0.65	9.5%
KC 2	480	28.8	0.53	1.8%	1.61	5.6%
Aldo - S1	480	5.9	0.25	4.2%	0.62	10.5%
Aldo - S2	480	8.8	0.27	3.1%	0.79	9.0%
Aldo - S3	480	18.5	0.42	2.3%	1.27	6.9%
Aldo - S4	480	29.8	0.78	2.6%	2.05	6.9%
Aldo - S5	480	50.4	1.16	2.3%	2.92	5.8%
Aldo - S6	480	82.6	1.76	2.1%	5.21	6.3%
Aldo - U1	480	7.4	0.26	3.6%	0.72	9.8%
Aldo - U2	480	44.1	1.24	2.8%	3.87	8.8%
Aldo – U3	480	76.3	1.91	2.5%	6.58	8.6%

Dilution Linearity:

Study Design

Samples of each sample type, serum, EDTA plasma and urine were diluted and analyzed by the LIAISON® Aldosterone assay following CLSI EP6-A. The results for each sample type were analyzed by a linear regression of Observed Aldosterone Concentration versus Expected Aldosterone Concentration.

Results

The resulting equation for serum sample is:
Observed LIAISON® Aldosterone = 0.994(Expected) + 0.71, R = 1.000

The resulting equation for EDTA plasma sample is:
Observed LIAISON® Aldosterone = 1.01(Expected) + 1.43, R =0.998

The resulting equation for urine sample is:
Observed LIAISON® Aldosterone = 0.996(Expected) + 0.69, R = 0.999

Interfering Substances

Controlled studies of potentially interfering substances at two Aldosterone levels in serum (15 and 30 ng/dL) and urine (5 and 15 ng/dL) showed no interference in the LIAISON® Aldosterone assay at the highest concentration for each substance listed below The testing was based on CLSI-EP7-A2.

Substance/Drug	Concentration Tested		Substance/Drug	Concentration Tested	
	Serum	Urine		Serum	Urine
Bilirubin (conjugated)	40 mg/dL	40 mg/dL	Propranolol	230 µg/dL	228 µg/dL
Bilirubin (unconj)	40 mg/dL	N/A	Metoprolol	1.28 mg/dL	1.28 mg/dL
Hemoglobin	600 mg/dL	600 mg/dL	Triamterene	886 µg/dL	886 µg/dL
Triglycerides	3000 mg/dL	3000 mg/dL	Spironolactone	60 µg/dL	60 µg/dL
Total protein	12 g/dL	12 g/dL	Tetracycline	1.51 mg/dL	1.51 mg/dL
Cholesterol	500 mg/dL	500 mg/dL	Amlodipine besylate	13.9 µg/dL	13.9 µg/dL
Creatinine	5 mg/dL	500 mg/dL	Nifedipine	40 µg/dL	43.9 mg/dL
Glucose	1 g/dL	1 g/dL	Verapamil	216 µg/dL	237 mg/dL
Ascorbic Acid	6 mg/dL	200 mg/dL	Furosemide	5.99 mg/dL	5.99 mg/dL
Urea	N/A	4 g/dL	Eplerenone	1.99 mg/dL	1.99 mg/dL
Boric Acid	N/A	2 g/dL	Enalapril	42.4 µg/dL	46.6 mg/dL
Acetic Acid	N/A	2%	Lisinopril	32.7 µg/dL	32.7 µg/dL
Acetaminophen	20 mg/dL	20 mg/dL	Losartan potassium	225 µg/dL	249 mg/dL
Acetylsalicylic acid	65.2 mg/dL	65.2 mg/dL	Valsartan	1.1 mg/dL	1.1 mg/dL
Salicylic acid	59.9 mg/dL	59.9 mg/dL	Hydrochlorothiazide (HCTZ)	600 µg/dL	600 µg/dL
Valproic Acid	57.6 mg/dL	57.6 mg/dL	Uric Acid	N/A	100 mg/dL
Tartaric Acid	N/A	1g/dL			

Cross-reactivity

Controlled studies of potentially cross reacting substances in serum and urine samples were performed on the LIAISON® Aldosterone assay at the concentrations listed below. All substances showed < 0.02% cross reactivity. The testing was based on CLSI EP7-A2.

The % cross reactivity is calculated as follows:

%Cross-Reactivity = (Mean_Corrected Assay Value/_Mean_Concentration Spiked)*100.

Where the corrected assay value = Mean_Aldosterone conc. of spiked sample – Mean Aldosterone conc. of the original sample (with vehicle).

Substance	Concentration ng/dL in Serum	Concentration ng/dL in Urine
Androstendione	10000	100000
Androsterone	100000	1000000
Corticosterone	100000	100000
18-OH-Corticosterone	100000	100000
Cortisol (Hydrocortisone)	100000	200000
Cortisone	200000	200000
21-Hydroxyprogesterone	100000	100000
11-Deoxycortisol	100000	100000
Dexamethasone	200000	200000
DHEA (trans-Dehydroandrosterone)	100000	1000000
Estradiol	100000	100000
Estriol	10000	100000
Estrone	10000	100000
Fludrocortisone	200000	200000
Prazosin HCl	1200000	1200000
Prednisone	100000	100000
Prednisolone	100000	100000
Pregnenolone	100000	100000
Progesterone	100000	100000
17 alpha Hydroxyprogesterone	100000	100000
Spironolactone	100000	100000
Testosterone	100000	200000

CONCLUSION:

The material submitted in this premarket notification is complete and supports the basis for substantial equivalence to the Siemens Coat-A-Count® Aldosterone assay (K831178). The labeling is sufficient and satisfies the requirements of 21 CFR 809.10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

DiaSorin
C/O Carol A. DePouw
1951 Northwestern Ave.
P. O. Box 285
STILLWATER MN 55082

Re: K130321
Trade/Device Name: LIAISON® Aldosterone
LIAISON® Aldosterone Control Set
LIAISON® Aldosterone Calibration Verifiers
Regulation Number: 21 CFR 862.1045
Regulation Name: Aldosterone test system
Regulatory Class: II
Product Code: CJM, JJX
Dated: February 07, 2013
Received: February 27, 2013

Dear Ms. DePouw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol E. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130321

Device Name: LIAISON® Aldosterone
LIAISON® Aldosterone Control Set
LIAISON® Aldosterone Calibration Verifiers

Indications for Use: The LIAISON® Aldosterone assay uses chemiluminescent immunoassay (CLIA) technology and is intended for the quantitative determination of Aldosterone in human serum, EDTA plasma and urine samples. Aldosterone measurements are intended for use in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states and other conditions of electrolyte imbalance.
The test has to be performed on the LIAISON® Analyzer.

The LIAISON® Aldosterone Control Set is intended for use as assayed quality control samples to monitor the accuracy of the LIAISON® Aldosterone assay on the LIAISON® Analyzer.

The LIAISON® Aldosterone Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® Aldosterone assay when performed on the LIAISON® Analyzer.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130321